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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,798	12/12/2001	Valentin Kramer	31567.3	9144
5251	7590	04/14/2005	EXAMINER	
SHOOK, HARDY & BACON LLP 2555 GRAND BLVD KANSAS CITY,, MO 64108			CHANG, VICTOR S	
			ART UNIT	PAPER NUMBER

1771

DATE MAILED: 04/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/017,798

Applicant(s)

KRAMER ET AL.

Examiner

Victor S. Chang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2005 and 03 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 19-32 is/are pending in the application.
- 4a) Of the above claim(s) 29-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-28 and 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Introduction***

1. The Examiner has carefully considered Applicants' amendments and remarks filed on 1/3/2005 and 3/3/2005. Applicants' amendments to cancel claims 1-18, and new claims 19-32 have been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Rejections not maintained are withdrawn. In particular, upon reconsideration, Applicants' argument "Looking to FIG. 2 of the application, it can be seen that one embodiment of the present invention includes a first plurality of fibrils interconnecting a first node with a second node ... a third node ... is shown between the first and second nodes ... A second plurality of fibrils ... may be seen in the figure as defining a plurality of small pores" is persuasive. As such, new claims 19-31 are entered. Additionally, in view of the substantially new scopes recited in new claims, the rejection over EP 0 402 901 is withdrawn. However, an additional search is required, and it yielded a new reference. The new reference is found to anticipate and/or render obvious the instant claimed invention. Applicant's comments regarding the prior art are moot in view of the new grounds of rejection.

### ***Election/Restrictions***

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:

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- I. Claims 19-28 and 32, drawn to an expanded PTFE article, classified in class 428, subclass 304.4.
- II. Claims 29-31, drawn to a method of making a PTFE article, classified in class 264, subclass 433.

The inventions are distinct, each from the other because of the following reasons:

5. Inventions Group II and Group I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to make other and materially different product, such as an ePTFE tube from a resin of single molecular weight distribution.
6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
7. During a telephone conversation with Marshall Honeyman on 4/6/2005 a provisional election was made without traverse to prosecute the invention of Group I, claims 19-28 and 32. Affirmation of this election must be made by applicant in replying to this Office action. Claims 29-31 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.
8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10. Claims 19-29 and 32 are rejected under 35 U.S.C. 102(a) as being anticipated by Edwin et al. (US 6039755).

Edwin's invention is directed to expanded microporous tubular polytetrafluoroethylene (ePTFE) grafts (abstract), which has a microstructure of nodes interconnected by fibrils, with the nodes being substantially perpendicular to the longitudinal axis of the tubular ePTFE material and the fibrils being oriented parallel to the longitudinal axis of the tubular ePTFE material, and radial expansion deforms the ePTFE microstructure by elongating the nodes. (column 2, lines 42-49).

For claims 19-21 and 28, the Examiner notes that while each embodiments shown by Edwin in Figs. 5A-24D arguable meets the structural recitation as claimed, the embodiments shown in Figs. 18D, 21B and 21D are particularly commensurate with the microstructure of the Fig. 2 (which, as argued by Applicants, is the basis of the new claims, as set forth above) of instant invention. Claims lack novelty.

For claim 22, Edwin expressly teaches that a wrap of PTFE tape is helically applied to the tubular PTFE (column 15, lines 5-10).

For claim 32, Edwin expressly teaches that the tubular ePTFE is used in vivo to restore an anatomical passageway or to create a passageway (column 1, lines 14-16), which is inherently a blood contacting application.

11. Claims 24-27 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Edwin et al. (US 6039755).

The teachings of Edwin are again relied upon as set forth above.

For claims 24-27, Edwin is silent about the ranges of the pore sizes. However, Edwin does show in Figs. 5A-24D embodiments which have fibril lengths corresponds to the pore sizes of instant invention. For example, Fig. 18D shows lengths of fibrils for small pores in the range of 2-15  $\mu\text{m}$ , and lengths of fibrils for large pores in the range of 20-50  $\mu\text{m}$ ; further, Fig. 18C shows the each of the large and small pores has a uniform fibril length distribution. As such, since Edwin teaches substantially the same subject matter (tubular ePTFE having the same microstructure) and for the same application (vascular graft), it is the Examiner's position that, in the absence of evidence to the contrary, a suitable pore size distribution of large and small pores are either anticipated by Edwin, or are obviously provided by practicing the invention of the prior art. It should be noted that where the claimed and prior art products are shown to be identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. See MPEP § 2112.01.

***Claim Rejections - 35 USC § 103***

**12.** Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Edwin et al. (US 6039755) in view of Myers et al. (US 5628782).

The teachings of Edwin are again relied upon as set forth above.

For claim 23, Edwin lacks an express teaching that the helical member is constructed of fluorinated ethylene propylene (FEP). However, it is noted that Myers' invention is directed to a vascular graft in the form of a tube (abstract), and Myers expressly teaches that PTFE and FEP films are used as wrap films for a vascular graft (column 5, lines 19-23). As such, in the absence of unexpected results, it would have been obvious to one of ordinary skill in the art to substitute Edwin's PTFE wrapping tape with an equivalent wrapping EFP tape of Myers'. It should be noted that the selection of and substitution of a known equivalent material based on its suitability for its intended use supported a *prima facie* obviousness determination. See MPEP § 2144.07.

***Conclusion***

**13.** Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

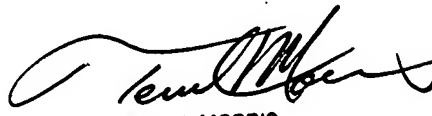
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor S. Chang whose telephone number is 571-272-1474. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel H. Morris can be reached on 571-272-1478. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*VSC*  
Victor S Chang  
Examiner  
Art Unit 1771

4/6/2005

  
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